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CHAPTER

5

**Single-incision and NOTES cholecystectomy;
are there clinical or cosmetic advantages
when compared to conventional
laparoscopic cholecystectomy?**

A case-control study comparing single-incision,
transvaginal, and conventional laparoscopic
technique for cholecystectomy.

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ABSTRACT

Background

The aim of the present study was to compare the clinical and cosmetic results of transvaginal hybrid cholecystectomy (TVC), single-port cholecystectomy (SPC), and conventional laparoscopic cholecystectomy (CLC). Recently, single-incision laparoscopic surgery and natural orifice transluminal endoscopic surgery have been developed as minimally invasive alternatives for CLC. Few comparative studies have been reported.

Methods

Female patients with symptomatic gallstone disease who were treated in 2011 with SPC, TVC, or CLC were entered into a database. Patients were matched for age, body mass index, and previous abdominal surgery. After the operation all patients received a survey with questions about recovery, cosmesis, and body image.

Results

A total of 90 patients, 30 in each group, were evaluated. Median operative time for CLC was significantly shorter ($p < 0.001$). There were no major complications. Length of hospital stay, postoperative pain, and postoperative complications were not significantly different. The results for cosmesis and body image after the transvaginal approach were significantly higher. None of the sexually active women observed postoperative dyspareunia.

Conclusions

SPC and TVC are feasible procedures when performed in selected patients. CLC is a faster procedure, but other clinical outcomes and complication rates were similar. SPC and especially TVC, offer a better cosmetic result. Randomised trials are needed to specify the role of SPC and TVC in the treatment of patients with symptomatic gallstone disease.

INTRODUCTION

Laparoscopic cholecystectomy has become the treatment of choice for symptomatic gallstone disease. Traditionally, laparoscopic cholecystectomy is performed through three or four small incisions. In an attempt to further minimise the impact of surgery, new techniques have been introduced, like single-incision laparoscopic surgery (SILS) and natural orifice transluminal endoscopic surgery (NOTES).¹⁻⁴ In theory, reducing surgical trauma by introduction of these new techniques might further improve the clinical results. Potential clinical benefits could be faster recovery and reduced postoperative pain scores. Another important reason for the development of these new techniques is the growing importance to patients of the cosmetic result.⁵⁻⁷ Nevertheless, the adoption of both new techniques has been slow, likely because of their perceived complexity and the fear of an increase in complications like common bile duct injuries. Other potential disadvantages could include procedure-related complications, like umbilical hernias in SILS cholecystectomy or dyspareunia after the transvaginal approach. The aim of the present study was to compare the clinical and cosmetic results of transvaginal hybrid cholecystectomy (TVC), single-port cholecystectomy (SPC), and conventional laparoscopic cholecystectomy (CLC). The SILS technique was introduced in our clinic in 2009 and has been used for cholecystectomies and colorectal surgery.⁸ Since the beginning of 2011, the hybrid NOTES cholecystectomy is also performed in our clinic.⁹

METHODS

Patient selection

Data regarding all female patients that were treated with a SPC or TVC from January 2011 until December 2011 was collected in a prospective database. Patients who underwent a CLC in 2011 by the same surgeons served as the control group for this study. Patients were specifically matched with respect to age, body mass index (BMI), and previous abdominal surgery. Group selection was done retrospectively by an independent researcher and was based on the aforementioned, preoperative variables.

The indication for surgery was symptomatic cholelithiasis, and diagnosis of gallstones was confirmed by ultrasound. All patients were classified as American Society of Anaesthesiologists (ASA) grades I or II. Exclusion criteria were cholecystitis (diagnosed on ultrasound or from elevated infection parameters), choledocholithiasis, and prior surgery in the small pelvis. In addition, patients had to be at least 18 years old, with no maximum age; the maximum BMI was 40. All patients were given the choice of whether to undergo SPC, CLC, or NOTES. Data collection included demographic data, BMI, ASA score, prior abdominal surgery, operative time, conversion rate, and perioperative complications. Operative time was calculated as time from first incision to time of completion of closure. Postoperative assessment was focussed on duration of hospital stay, pain scores, and recovery.

Patients were given a standardised dose of paracetamol 4 times 1 gram in 24 hours.

Postoperatively, all patients were provided with a patient-controlled analgesia (PCA) pump, with each PCA dose consisting of 1.5 milligrams of morphine. Pain scores and the number of times that the PCA pump was used were recorded for the first 24 hours postoperatively by an independent researcher. Pain scores were assessed with the numeric rating scale.

Informed consent was received from all patients, and Institutional Review Board (IRB) approval was obtained before introduction of the SILS and NOTES techniques in our institution.

Surgical technique

All patients were treated by at least one member of a team of two experienced laparoscopic surgeons and two senior residents specialising in laparoscopic surgery. Antibiotic prophylaxis was only administered in the NOTES group; preoperatively those patients received 2 grams of cefazolin and 1 gram of metronidazole.

The technique used for CLC was the standard four trocar approach described in many reports (10 mm optic at the umbilicus, 10 mm trocar in the epigastrium, two 5 mm trocars in the right upper abdomen). Our technique for SPC has been described in detail.¹⁰ The umbilicus was everted and opened longitudinally, after which a SILS port (Covidien, Mansfield, MA, USA) was introduced. Retraction and manipulation of the gallbladder was achieved with Vicryl sutures; normal straight laparoscopic instruments were used to dissect Calot's triangle. The umbilical fascia was closed with interrupted resorbable sutures, and the umbilicus was restored with intracutaneous resorbable sutures.

The TVC was performed as a hybrid technique as previously described by Zornig et al.¹ A 5 mm trocar was inserted through the umbilicus with a 5 mm optic. Under direct vision and with the patient in the Trendelenburg position, a vaginal trocar with a 10 mm optic and a 5 mm forceps was introduced through the fornix posterior. With the patient in the anti-Trendelenburg position, the gallbladder was fixed at the ventral abdominal wall with a percutaneous suture through the fundus of the gallbladder. The dissection was conducted with a working instrument through the umbilical port. After critical view of safety was reached, the cystic artery and cystic duct were clipped with Hem-o-lok clips (Teleflex Medical, Research Triangle Park, NC, USA).¹¹ A removal bag was used to withdraw the gallbladder through the fornix posterior. The defect in the fornix posterior was closed with resorbable sutures. Patients were advised to abstain from sexual intercourse for 4–6 weeks.

Insertion of an extra trocar during SPC or TVC was considered as a conversion to conventional laparoscopy.

Postoperative survey

All patients received a survey at least 10 weeks after surgery, either as a web-based document or, on request, by regular mail. This questionnaire had two main components; a body image questionnaire (BIQ) (appendix 1) and a series of questions regarding recovery and sexual activity following surgery.

The BIQ is an eight-item questionnaire incorporating body image and cosmetic subscales, each with a high internal consistency (Cronbach's α of 0.80 and 0.83, respectively).¹² The body image scale investigates a patient's perception and satisfaction with her body after surgery; the cosmetic scale measures the patient's satisfaction with the surgical scars.

Statistical analysis

Continuous data were presented as median and range or mean \pm standard deviation (SD).

Dichotomous and categorical data were presented as numbers with percentages. If the data were not normally distributed, continuous data were assessed using the Kruskal-Wallis test for overall differences, and post hoc analysis was conducted using the Mann-Whitney U test for differences between groups. The Chi square test was used for categorical data.

A two-sided p-value of ≤ 0.05 was considered statistically significant. Statistical analyses were performed with the Statistical Package for the Social Sciences, version 20.0 (SPSS, Chicago, IL, USA).

RESULTS

Operative results

During the period from January 2011 until December 2011, 40 TVC were performed at our institution. A total of 34 groups (consisting of three patients each) could be matched from this patient pool. Three patients could not be contacted and one patient refused to participate, thus enrolling a total of 90 patients in this study. Baseline characteristics are shown in table 1. The three groups of patients were well matched with regard to age, BMI, and previous abdominal surgery.

Table 1. Patient demographics

No. of patients	Laparoscopic cholecystectomy			p-value
	CLC	SPC	TVC	
No. of patients	30	30	30	
Age (years), median (range)	46 (24-70)	43 (18-62)	42 (18-62)	0.13*
Gender (%)				1.0
Female	30 (100)	30 (100)	30 (100)	
Male	-	-	-	
BMI (kg/m ²), median (range)	27 (20-40)	25 (20-38)	25 (18-33)	0.09*
Previous abdominal surgery, n (%)	6 (19)	4 (13)	6 (19)	0.74 [‡]

* *Kruskal-Wallis test*, [‡] *Chi-square test*, CLC conventional laparoscopic cholecystectomy, SPC single-port cholecystectomy, TVC transvaginal cholecystectomy

The median time needed to perform a CLC was 46 min (range 28-75 min); for SPC, 55 min (range 40-96 min); and for TVC, 60 min (range 44-87 min) (figure 1). The operative time is statistically

significant in favour of CLC ($p < 0.001$); no difference was seen between the SPC and TVC groups ($p = 0.311$).

All operations were performed successfully without conversion to an open procedure. However, in the SPC and TVC groups, it was necessary to place extra trocars in two patients in order to obtain a critical view with safety. There were no intraoperative complications in the three groups, and intraoperative cholangiography was not performed. All patients were discharged on the first postoperative day.

Wound infections were not observed in the TVC group. After CLC there was one wound infection, and after SPC there were two wound infections. In the entire population only one hernia developed, in a patient after SPC who had a wound infection.

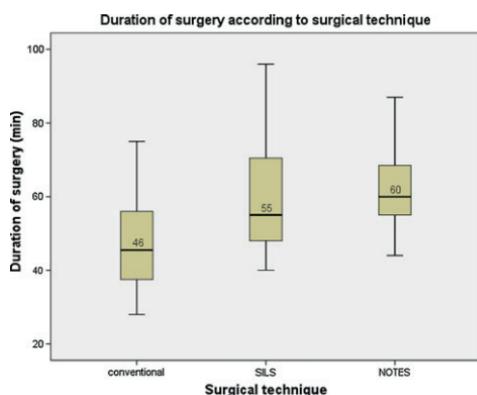


Figure 1. Duration of surgery according to surgical technique

SILS single-incision laparoscopic surgery, *NOTES* natural orifice transluminal endoscopic surgery

With respect to pain scores and postoperative use of analgesic drugs, no statistically significant differences were observed among the three groups (table 2). Post hoc analysis also did not show significant differences in intergroup comparisons.

Body image questionnaire

All patients treated in this study were satisfied with the result as BIQ scores were high in the entire population.

Table 2. Postoperative outcomes and results of the body image questionnaire according to surgical approach

	Laparoscopic cholecystectomy			p-value
	CLC	SPC	TVC	
Pain scores, median (range)	2 (0-4)	1 (1-4)	2 (0-5)	0.068*
Analgesic drugs (doses), median (range)	7 (1-16)	5 (1-14)	5 (0-12)	0.463*
Postoperative hospital stay in days, median	1 19 (15-20)	1 20 (16-20)	1 20 (17-20)	-
Body image score, median (range)				0.007 [‡]
CLC vs SPC				<0.001 [‡]
CLC vs TVC				0.99 [‡]
SPC vs TVC	19 (9-24)	22.5 (10-24)	24 (23-24)	
Cosmetic score, median (range)				
CLC vs SPC				<0.001 [‡]
CLC vs TVC				<0.001 [‡]
SPC vs TVC				<0.012 [‡]

* *Kruskal-Wallis test*, [‡] *Mann-Whitney test*, CLC conventional laparoscopic cholecystectomy, SPC single-port cholecystectomy, TVC transvaginal cholecystectomy

However, scores for the body image subscale and cosmetic subscale were significantly higher in the TVC and SPC groups when compared to the CLC patients. Analysis for SPC and TVC showed a statistical difference for cosmesis, but not for body image, in favour of TVC. Median self-scar ratings for the three groups are shown in figure 2. There was no statistical difference between the intervals from surgery to survey completion for the three groups.

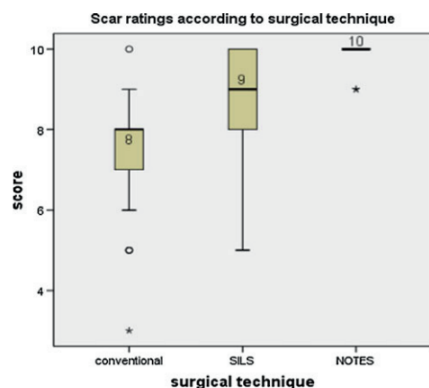


Figure 2. Scar ratings according to surgical technique.

SILS single-incision laparoscopic surgery, *NOTES* natural orifice transluminal endoscopic surgery

Recovery questionnaire

Although the difference was not significant, 46 percent of the women in the TVC group returned to their normal daily routine within 10 days, compared with 25 and 34 percent for CLC and SPC, respectively. More than 75 percent of the women were sexually active after surgery, and there was no difference among the three groups. Time to first sexual postoperative intercourse and the number of women that were sexually less active postoperatively were also not statistically significant. None of the sexually active women experienced dyspareunia postoperatively.

DISCUSSION

We present the results of our case-control study comparing conventional laparoscopic surgery with a SILS and a NOTES procedure for cholecystectomy.

Operative times were significantly shorter with the classic laparoscopic approach in this study. Our operative times for both SPC and TVC are reasonable and correspond well with operative times reported in the literature.¹³ However, a recent study comparing the three different techniques for cholecystectomy did not observe differences between the procedures with regard to the length of the operation.¹⁴

There were no major complications, proving that TVC and SPC are safe and feasible when performed by experienced laparoscopic residents or surgeons. The number of conversions was

low and is subordinate to reaching a critical view of safety. Only one hernia occurred, in the SPC group. Single-port surgery could potentially cause more abdominal hernias, as the defect in the fascia is larger than with CLC. Long-term follow-up of single-port surgery is still awaited and should address this topic. Trocar hernias after a TVC are not expected, as hernias after insertion of a 5 mm trocar are rare.¹⁵

A recent meta-analysis of 2626 patients concluded that SPC is associated with a higher rate of bile duct injury.¹⁶ Although we did not observe bile duct injuries after SPC, we support “the word of caution” in this article. In our opinion, SPC is technically the most demanding procedure of the three procedures that we performed in this study.

One of the most discussed potential benefits of the new minimally invasive techniques is an improved cosmetic result. With the development of these new techniques, research has been focusing on patient satisfaction and body image after surgery.¹⁷⁻²⁰ Body image is a strong determinant of patient satisfaction and evaluation of the (subjective) benefits of different types of surgery.²¹ Dunker et al. developed a widely used survey for body cosmesis and body image.^{12,22,23} In their survey, cosmetic consequences of scarring and body image were investigated using a questionnaire. A validated survey for patient-reported outcomes of scar assessment after abdominal surgery is currently not available.²⁴

This study clearly shows a significant difference in body image and cosmesis in favour of TVC and SPC when compared to CLC. The BIQ scores were high in the entire study population, which we expected as a laparoscopic cholecystectomy is only a minor surgical intervention with a short hospital stay and minor scars. Although the cosmetic subscale scores were statistically significant between SPC and TVC, the absolute difference in scores between the two groups is rather small and therefore probably not clinically relevant. Scores in the cosmetic subscale were extremely high in the TVC group; all patients scored 23 or 24 points with 24 points being the maximum score possible. This observation confirms the potential of NOTES procedures with respect to an excellent cosmetic outcome.

A recent retrospective study among 195 women concluded that patients after CLC rated their scars as excellent and that SPC has a limited role in improving cosmesis.²⁵ Our study has proven the opposite; the absence of visible scars with the transvaginal approach is better rated than the conventional approach. An explanation for these conflicting conclusions could be that patients in the study by Bignell et al. had no comparison with other cholecystectomy techniques, as we offered in our study. Bignell et al. also did not mention other possibilities for cholecystectomy in

their survey, and it is unlikely that all questioned patients had knowledge of SILS and NOTES techniques, as overall awareness of these new techniques is still low.

Another alleged advantage of new minimally invasive procedures like NOTES and SILS is less postoperative pain and faster recovery. A recent randomised trial has demonstrated a significantly better pain profile and reduced use of postoperative analgesics after SPC.⁶ Several other trials did not find differences between CLC and SPC.^{5,26} Moreover, intermediate results of a multicentre randomised trial showed that SPC pain scores are higher compared to CLC.²⁷ It therefore remains controversial whether postoperative pain profiles are better after SPC.

Randomised trials comparing TVC with other techniques are not yet available, but a recent large matched-pair analysis showed no significant difference when compared to CLC.²⁸ Our study showed no difference in pain profiles and use of postoperative analgesics during the first 24 hours. In contrast with the first 24 hours, we observed a difference in postoperative recovery during the first 10 days in favour of the vaginal approach. After TVC, 46 percent of the women returned to their normal daily routine (work, study) within 10 days, compared to 25 and 34 percent for CLC and SPC, respectively. Because of the small population in our study, these numbers are not statistically significant. It may be that the pain in the immediate postoperative period is caused primarily by the pneumoperitoneum, whereas recovery in the first 10 days is more determined by the presence or absence of incisions through the abdominal wall.

With the introduction of NOTES, and transvaginal procedures in particular, concerns were raised about postoperative sexual function, fertility, and dyspareunia. Recent surveys mention these particular reasons as a major threshold for future transvaginal surgery among women. Whether these concerns are prejudices or realistic concerns remains unclear, as data on follow-up are scarce. Our survey with small groups and limited follow-up suggests that there is no difference from conventional surgery as none of our patients had postoperative dyspareunia. Even the time between surgery and first postoperative sexual intercourse did not differ among the three groups. A recent study by Zornig et al. supports our results, as they also did not record sexual complaints in their transvaginal study group.²⁸ In order to take away the fears with regard to sexual function, larger trials and longer follow-up are needed in future research.

Recent studies have shown a preference for SILS when compared to conventional laparoscopy and NOTES.^{17,18,29,30} These studies were all conducted with questionnaires in a healthy population. Bucher et al. described a preference of 87 percent for a SPC in a female population.²⁹ All patients in our study were asked which technique they would prefer if they had the option to choose again. Interestingly, 52 percent of our population expressed a preference for a NOTES procedure, 42 percent would undergo a SILS procedure, and a minority of 6 percent would opt for the conventional laparoscopy. Of the women treated with a TVC, 93 percent would choose a TVC again. In our opinion, this difference in preferences can be attributed to the unfamiliarity of the general population with NOTES.³⁰ Several studies have suggested that younger women are most concerned with cosmesis and that they would be an ideal group for a treatment by the transvaginal approach.^{29,30} The median age of the women who selected NOTES as their preference in our study was 42 years, so we think a much larger group of women should be considered for a NOTES procedure.

We are aware that this study has several limitations. First, it is not a randomised trial. This introduces a bias in our pre-surgical counselling as to which treatment was offered to a patient. However, in our opinion it would be very difficult to investigate TVC in a randomised trial at this moment. A lot of female patients express a strong preference pro or contra the transvaginal approach and it is not likely that they were willing to be randomised.

Second, a validated survey for scar assessment and body image is still not available. However, the BIQ is widely used in surgical literature for assessment of body image and cosmesis in abdominal surgery and has a high internal consistency.

Finally, the number of treated patients in the three different groups is small.

Despite these limitations, we believe that this study provides a valuable insight into the value of clinical and cosmetic outcomes for SILS and NOTES techniques among women. A randomised trial with larger groups is necessary to further specify the role of SPC and TVC in the treatment of female patients with symptomatic gallstone disease.

CONCLUSIONS

Both SPC and TVC are safe and feasible procedures when performed in selected patients. Although the CLC is faster, SPC and especially TVC offer advantages in body image and cosmesis for women with symptomatic gallstone disease.

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APPENDIX 1 – BODY IMAGE QUESTIONNAIRE

BIQ consisting of a body image score (items 1-5) and a cosmetic score (items 6-8)

1. Are you less satisfied with your body since the operation?

1. No, not at all
2. A little bit
3. Quite a bit
4. Yes, extremely

2. Do you think the operation has damaged your body?

1. 1. No, not at all
2. A little bit
3. Quite a bit
4. 4. Yes, extremely

3. Do you feel less attractive as a result of your operation?

1. No, not at all
2. A little bit
3. Quite a bit
4. Yes, extremely

4. Do you feel less feminine as a result of your operation?

1. No, not at all
2. A little bit
3. Quite a bit
4. Yes, extremely

5. Is it difficult to look at yourself naked?

1. No, not at all
2. A little bit
3. Quite a bit
4. Yes, extremely

6. On a scale from 1 to 7, how satisfied are you with your scar(s)?

1. Very unsatisfied
2. Quite unsatisfied
3. A bit unsatisfied
4. Not unsatisfied/not satisfied
5. A bit satisfied
6. Quite satisfied
7. Very satisfied

7. On a scale from 1 to 7, how would you describe your scar(s)?

1. Revolting
2. Quite revolting
3. A bit revolting
4. Not revolting/not beautiful
5. A bit beautiful
6. Quite beautiful
7. Very beautiful

8. Could you score your own incisional scar(s) on a scale from 1 to 10?

Recovery questionnaire

1. Do you feel reserved in establishing/maintaining (a) sexual relationship(s) since the operation?

1. No, not at all
2. A little bit
3. Quite a bit
4. Yes, extremely
5. Not applicable

2. Has there been a change in sexual activity since the operation?

1. Yes, much less active
2. Yes, a little less active
3. No
4. Yes, a little more active
5. Yes, much more active
6. Not applicable

3. Did you have sexual intercourse since the operation?

1. Yes, within 2 weeks
2. Yes, between 2 and 4 weeks
3. Yes, after 4 or more weeks
4. No, as a result of the operation (discomfort/pain)
5. Not applicable

4. If 'yes' to question 3, did anything changed compared to before the operation (for instance: pain, embarrassment, etc.?)

1. No
2. Yes
3. Yes, other reasons than pain

5. On a scale from 1 to 10, how would you score your self-confidence?
6. How long was the period of your sick leave? How many days did you remain off work?
1. Not applicable (no work/study)
 2. 1 to 5 days
 3. 5 to 10 days
 4. More than 10 days, i.e. [...] days
7. Do you feel generally healthy?
1. Yes, extremely
 2. Quite a bit
 3. A little bit
 4. No, not at all
8. Would you recommend the operation you had?
1. Yes
 2. No
9. If you needed the same surgery again, which technique would you prefer most and which technique would you prefer last?

(The English translation was performed for this publication only and has not been validated clinically.)